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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

20 DEC 2004

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 639019C:ANB:NXL	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. PCT/AU2003/000772	International Filing Date (day/month/year) 20 June 2003	Priority Date (day/month/year) 20 June 2002
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ A61K 7/16, A61K 35/20, A61K 38/17, A23J 1/20, A61P 1/00		
Applicant PACIFIC-BIOLINK PTY LIMITED et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet. <input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of sheet(s).
3. This report contains indications relating to the following items: I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application

Date of submission of the demand 15 October 2003	Date of completion of the report 6 October 2004
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer M. Ong Telephone No. (02) 6283 2491

I. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	YES
	Claims 1-39	NO
Inventive step (IS)	Claims	YES
	Claims 1-39	NO
Industrial applicability (IA)	Claims 1-39	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

Novelty (N): Claims 1-39

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1: WO 00/06108 A
D2: WO 94/00146 A
D3: WO 82/03008 A
D4: US 5 958 915 A
D5: WO 97/40811 A
D6: Herod, EL (1994)
D7: Whitney, R (1988)
D8: Hay KD et al (2002)

The invention is directed to a formulation comprising a water soluble or water-dispersible form of an isolated and purified casein phosphoprotein or salt thereof, for example α -casein, β -casein, κ -casein and mixtures thereof, optionally complexed with at least one bioactive constituent in the form of calcium phosphate or calcium phosphate admixed with at least one other bioactive, for example an antimicrobial agent and additionally a salivary stimulator. The invention is further directed to methods of lubricating the oral cavity, treatment and/or prevention of xerostomia, mouth odour or halitosis, tooth decay and method of providing one or more vitamin and/or minerals in an animal. It further includes a process for the preparation of the oral lubrication formula.

D1 discloses a formulation comprising a water soluble isolated and purified casein protein or salt thereof such as α -casein, β -casein, κ -casein and mixtures thereof, together with at least one bioactive constituent including an antimicrobial, calcium phosphate, vitamins etc. Viscosity modifiers such as sodium carboxymethyl cellulose, hydroxyethylpropylcellulose, hydroxybutyl methyl cellulose, hydroxy ethyl cellulose (Natrosol) and colloidal silica eg. finely ground Syloid is disclosed, along with salivary stimulators eg. oil of spearmint, peppermint, wintergreen, sassafras etc. Formulations are incorporated in lozenges, chewing gum, mouthwashes, toothpaste or gels. Methods of treating or preventing dental caries, tooth erosion, gingivitis and mouth odour are further encompassed in D1. An optionally sprayed dried preparation of the formulation, derived from the mixing of a casein salt and calcium ions is further taught.

D2 teaches an antibacterial, anticaries or antiplaque oral composition in the form of a mouthwash, toothpaste, gel, tablet, lozenge, chewing gum etc comprising casein, a component of casein or casein phosphopeptides, together with calcium phosphate and other actives such as zinc, copper, stannous, sweeteners, abrasives etc.

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of V

D3-D5 similarly disclose oral antibacterial compositions comprising water soluble casein phosphoproteins and other common additives, such as viscosity modifiers and flavourings that can act as salivary stimulators etc. Treatment of mouth odour and tooth decay is particularly exemplified in D3.

D7 teaches casein phosphoproteins and its interactions with calcium and phosphate whilst D8 discloses the anticaries efficacy of casein derivatives coupled with calcium phosphate as a mouthrinse in patients with dry mouth (xerostomia).

In the light of each of these citations, claims 1-39 lack novelty.

Inventive Step (IS): Claims 1-39

As above.

The claims further lack an inventive step with respect to the methods of treatments (claims 25-36) since the provision of and use of a mouthwash for instance acts to lubricate the oral cavity, thus preventing xerostomia, mouth odour and similar symptoms. D1-D3 have furthermore disclosed oral compositions for the prevention of tooth decay, gingivitis plaque formation etc, known causes of halitosis. The addition of common ingredients in oral formulations such as oil of peppermint and antibacterials in mouthwash, toothpaste, chewing gum and the like constitute common general knowledge in the art. Further, there is no evidence in the present application to support that common flavourings such as oil of spearmint, peppermint etc act as a salivary stimulator and as such the subject matter of the claims cannot be distinguished from the formulations of the prior art.

The invention in claims 28-31 also lacks an inventive step in view of D6. The document teaches the use of milk as a saliva substitute. It is taught that milk has many chemical and physical properties of a good saliva substitute and that anticariogenic factors are generally attributed to the high calcium and phosphate content along with milk phosphoproteins eg. casein phosphopeptides. Milk was clearly recommended to benefit most patients with xerostomia. Hence the skilled person would be expected to arrive at the claimed invention in view of any one of the disclosures in D6 and D1-D5 or D8.

Industrial Applicability (IA): Claims 1-39

Claims 1-39 have industrial applicability.